510(K) SUMMARY

DEC 1 1 2012

A. Device Name

Proprietary Name	Glidesheath Slender
Classification Name	Catheter Introducer (as per 870.1340)
Common Name	Introducer Sheath
Product Code	DYB

B. Intended Use

The Glidesheath Slender is used to facilitate placing a catheter through the skin into the radial artery.

C. Predicate Device

Terumo Corporation, Glidesheath (K082644)

D. Device Description

The Glidesheath Slender consists of an introducer sheath and a dilator which are packaged together with an entry needle and mini guide wire. The Glidesheath Slender is used to facilitate placing a catheter through the skin into the radial artery. The sheath and dilator contain bismuth, making these devices visible under fluoroscopy. The sheath is coated with hydrophilic coating to minimize frictional resistance when inserting or removing the sheath from the patient's blood vessel.

The entry needle (cannula) is used to gain access to the radial artery for placement of the mini guide wire. The entry needle is offered in two versions, either a stainless steel needle or a Surflo IV catheter (K891087).

The mini guide wire is used for placement of the sheath and dilator into the radial artery. The mini guide wire is offered in two versions, either a stainless steel (spring coil) model or a polyurethane (nitinol core) plastic model.

A guide wire inserter is also provided to assist in insertion of the mini guide wire into the cannula.

E. Principle of Operation

The Glidesheath Slender is operated manually or by a manual process. This is the same principle of operation of the predicate Glidesheath device.

F. Technological/Design Comparison

The Glidesheath Slender submitted in this 510(k) and the Glidesheath cleared under K082644 contain the same basic components. Specification differences do not raise any new issues of safety and effectiveness.

Specification	Glidesheath (K082644)	Glidesheath Slender
Sheath Sizes	4, 5 and 6Fr	6Fr
Sheath Tip ID (6Fr)	2.10mm	2.10mm
Sheath OD (6Fr)	2.62mm	2.46mm
Sheath Length	10, 16 and 25cm	10 and 16cm
Sheath Coating	Hydrophilic (entire length of shaft)	Hydrophilic (entire length of shaft)
Dilator Length	15.5cm - 30.5cm	15.5cm - 21.5cm
Stainless Steel Guide Wire OD	.021" - .038"	.018" - .035"
Stainless Steel Guide Wire Length	10cm –180cm	45cm – 80cm
Plastic Guide Wire OD	.021" - .038"	.018" - .035"
Plastic Guide Wire Length	45cm – 80cm	45cm – 80cm
Metallic Entry Needle Size	20G – 21G	20G – 22G
Metallic Entry Needle Length	1.5"	1.5"
Surflo IV Catheter Size	16G – 22G	18G – 22G
Surflo IV Catheter Length	1" – 2.5"	1" – 2.5"

G. Materials Comparison

The Glidesheath Slender submitted in this 510(k) and the Glidesheath cleared under K082644 are manufactured from identical materials.

Component	Glidesheath (K082644)	Glidesheath Slender
Sheath Tubing	ETFE, Bismuth	ETFE, Bismuth
Hydrophilic Coating	Dimethyl acrylamide-glycidyl methacrylate copolymer	Dimethyl acrylamide-glycidyl methacrylate copolymer
Sheath Housing	Polypropylene	Polypropylene
Sheath Caulking Pin	Stainless Steel	Stainless Steel
Sheath Cap	Polypropylene	Polypropylene
Sheath Valve	Silicone Rubber	Silicone Rubber
Sheath Support	Styrene-ethylene-butylene-styrene block copolymer	Styrene-ethylene-butylene-styrene block copolymer
Side Tube	Polybutadiene	Polybutadiene
3-Way Stopcock	Polyethylene, Polypropylene, Polycarbonate	Polyethylene, Polypropylene, Polycarbonate
Dilator Tube	Polypropylene	Polypropylene

Dilator Hub	Polypropylene	Polypropylene
Dilator Caulking Pin	Stainless Steel	Stainless Steel
Plastic Guide Wire	NiTi, Tungsten, Polyurethane	NiTi, Tungsten, Polyurethane
Metallic Guide Wire	Stainless Steel	Stainless Steel
Guide inserter	Polyethylene	Polyethylene
Metallic Needle	Stainless Steel	Stainless Steel
Metallic Needle Hub	Styrene-butadiene copolymer	Styrene-butadiene copolymer
IV Catheter Tube	ETFE, Barium sulfate	ETFE, Barium sulfate
IV Catheter Hub	Polypropylene	Polypropylene
IV Catheter Caulking Pin	Stainless Steel	Stainless Steel
IV Catheter Filter Cap	Polystyrene, Polyester-Chlorinated polyethylene	Polystyrene, Polyester-Chlorinated polyethylene
IV Catheter Adapter	Polypropylene	Polypropylene
IV Catheter Needle	Stainless Steel	Stainless Steel
IV Catheter Needle Hub	Polycarbonate	Polycarbonate

H. Performance Testing

The following bench tests were performed to verify that the subject device is substantially equivalent to the predicate device and that there are no new issues regarding the safety and effectiveness of the device:

Performance Testing Sheath	Method
Surface	ISO 11070 Sec. 4.3
Corrosion resistance	ISO 11070 Sec. 4.4
Radiodetectability	ISO 11070 Sec. 4.5
Dimensional verification	ISO 11070 Sec. 7.2
Freedom from leakage (sheath)	ISO 11070 Sec. 7.3
Freedom from leakage (hemostasis valve)	ISO 11070 Sec. 7.4
Force at break (sheath)	ISO 11070 Sec. 7.6
Force at break (sheath to hub)	ISO 11070 Sec. 7.6
Sheath to dilator fit	ISO 11070 Sec. A.1
Rollback test	ISO 11070 Sec. A.1
Puncture model test	ISO 11070 Sec. A.1
Flexibility (kink angle)	ISO 11070 Sec. A.1
Flexibility (radius of curvature)	ISO 11070 Sec. A.1
Catheter insertion resistance	Internal Standard
Penetration resistance	Internal Standard
External surface sliding performance	Internal Standard
Hydrophilic coating separation resistance	Internal Standard
Hydrophilic coating particulate evaluation	FDA Guidance[1], USP788

[1] *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*

Performance Testing Dilator	Method
Surface	ISO 11070 Sec. 4.3
Corrosion resistance	ISO 11070 Sec. 4.4
Dimensional verification	ISO 11070 Sec. 9.2
Conical fitting	ISO 11070 Sec. 9.3.2 ISO 594-1
Strength of union (dilator to hub)	ISO 11070 Sec. 9.3.3

Performance Testing Stainless Steel Needle	Method
Surface	ISO 11070 Sec. 4.3
Corrosion resistance	ISO 11070 Sec. 4.4
Radiodetectability	ISO 11070 Sec. 4.5
Dimensional verification	ISO 11070 Sec. 5.2
Needle point	ISO 11070 Sec. 5.3
Conical fitting	ISO 11070 Sec. 5.4.1, ISO 594-1
Strength of union (needle tube to hub)	ISO 11070 Sec. 5.4.2

Performance Testing Surflo IV Needle	Method
Surface	ISO 11070 Sec. 4.3
Corrosion resistance	ISO 11070 Sec. 4.4
Radiodetectability	ISO 11070 Sec. 4.5
Dimensional verification	ISO 11070 Sec. 5.2
Needle point	ISO 11070 Sec. 5.3
Conical fitting	ISO 11070 Sec. 5.4.1, ISO 594-1
Strength of union (needle tube to hub)	ISO 11070 Sec. 5.4.2

Performance Testing Surflo IV Catheter	Method
Surface	ISO 11070 Sec. 4.3
Corrosion resistance	ISO 11070 Sec. 4.4
Radiodetectability	ISO 11070 Sec. 4.5
Catheter to needle fit	ISO 11070 Sec. 6.2
Strength of union (catheter to hub)	ISO 11070 Sec. 6.3
Conical fitting	ISO 11070 Sec. 6.4, ISO 594-1
Dimensional verification	ISO 11070 Sec. 6.5

Performance Testing Plastic Guide Wire	Method
Surface	ISO 11070 Sec. 4.3
Radiodetectability	ISO 11070 Sec. 4.5
Dimensional verification	ISO 11070 Sec. 8.2
Test for fracture of guide wire	ISO 11070 Sec. 8.4
Resistance to damage by flexing	ISO 11070 Sec. 8.5

Performance Testing Stainless Steel Guide Wire	Method
Surface	ISO 11070 Sec. 4.3
Corrosion resistance	ISO 11070 Sec. 4.4
Radiodetectability	ISO 11070 Sec. 4.5
Dimensional verification	ISO 11070 Sec. 8.2
Test for fracture of guide wire	ISO 11070 Sec. 8.4
Resistance to damage by flexing	ISO 11070 Sec. 8.5
Strength of union of safety wire and coil	ISO 11070 Sec. 8.6
Strength of union of core wire and coil	ISO 11070 Sec. 8.7

I. Biocompatibility

Biocompatibility of Glidesheath Slender was evaluated based on ISO10993-1 : 2009. The Glidesheath Slender including Sheath, Dilator, Guidewire, and Entry needle are classified as Externally Communicating Devices, Circulating Blood, Limited Contact (<24 hrs). This is the same classification as the predicate Glidesheath (K082644).

All of the materials and manufacturing processes used to fabricate the Glidesheath Slender are identical to the Glidesheath predicate device cleared in K082644.

Glidesheath Slender has the same body contact, contact duration, blood contacting materials, manufacturing processes and sterilization method as the Glidesheath predicate device (K082644). Additionally, the Glidesheath product line has a demonstrated history of safe and effective use. We conclude therefore that the Glidesheath Slender is biocompatible for its intended use.

J. Sterilization

Sterilization conditions have been validated according to ANSI / AAMI / ISO 11135, Sterilization of Health Care Products– Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, to provide a Sterility Assurance Level (SAL) of 10-6.

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) residuals will meet requirements for limited exposure devices (contact up to 24 hours) prior to use, based on ISO 10993-7, Biological Evaluation of medical devices- Part 7: Ethylene Oxide Sterilization residuals. Residual EO will not exceed 4 mg per device and residual ECH will not exceed 9 mg per device.

K. Additional Safety Information

The Glidesheath Slender is certified to be non-pyrogenic in the unopened and undamaged package. Kinetic Turbidimetric Limulus Amebocyte Lysate (LAL) test is performed on each lot of production in accordance with the United States Pharmacopoeia (USP) <85> Bacterial Endotoxins Test. Validation was performed in accordance with FDA published "Guideline on

Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices"; 1987.

Potential release of TiO2 particles from the Glidesheath Slender was evaluated using both non-polar and polar extracts in accordance with ISO10993-12. Results demonstrated that potential release of titanium dioxide per product was much lower than the tolerable intake calculated from the No Observable Adverse Effect Level (NOAEL) and therefore, does not raise a safety concern.

L. Substantial Equivalence

The Glidesheath Slender is substantially equivalent in intended use, principles of operation, design/technology, materials and performance to the predicate device the Glidesheath (K082644). Differences between the devices do not raise any new concerns of safety or effectiveness.

M. Submitter Information

Prepared By:	Mr. Daniel R. Plonski, RAC Sr. Regulatory Affairs Specialist
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Date Prepared:	September 25, 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DEC 1 1 2012

Terumo Medical Co.
Daniel Plonski, Senior Regulatory Affairs Specialist
950 Elkton Blvd
Elkton, MD 21921

Re: K122980
Trade/Device Name: Glidesheath Slender introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 25, 2012
Received: September 26, 2012

Dear Daniel Plonski,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram Zuckerman, M.D.
Director
Division of Cardiac Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122980

Device Name: Glidesheath Slender™

Indications For Use:

The Glidesheath Slender is used to facilitate placing a catheter through the skin into the radial artery.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122980